



Arizona State Board of Pharmacy
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**THE ARIZONA STATE BOARD OF PHARMACY
HELD A COMPOUNDING TASK FORCE MEETING ON AUGUST 23, 2013**

MINUTES FOR COMPOUNDING TASK FORCE MEETING

Call to Order – August 23, 2013

Chairman John Musil convened the meeting at 2:00 P.M. and welcomed the audience to the meeting.

Roll Call

The following Task Force Members were present: Chairman John Musil, Rich Monty (via telephone), Dana Reed-Kane (via telephone), Eric Bauer, Linda Carboni, Dennis Waggoner, Danielle Evans, and Sandra Sutcliffe. Tom Van Hassel was not present. Board Staff present: Cheryl Frush- Deputy Director

Review of Article 4-23-110 – Definitions

Chairman Musil opened the discussion by asking if there were any changes or comments concerning the definitions.

Ms. Sutcliffe stated that the definitions that were added were definitions taken from USP 797 or USP 795. Ms. Sutcliffe stated that some definitions have been left blank and she would be researching those definitions.

Mr. Musil asked that the definition for Iso Class 8 be added to the definitions.

Mr. Musil asked that fungi be added to the definition for Risk Level.

Review of Article 4-23-410

Mr. Musil questioned why in B (2) (a) the certificate of analysis would need to be kept for 7 years. Ms. Sutcliffe stated that prescription records must be kept for 7 years.

Ms. Sutcliffe stated that she would be adding in Section E the use of the NIOSH list for Antineoplastic drugs and other hazardous drugs that should be made in a powder hood or designated area.

Mr. Monty asked about having distinct areas for the clean room and ante room. Mr. Musil stated that would depend on the type of compounding being done. Ms. Sutcliffe stated that the definition for the ante room came from USP 797.

Ms. Carboni asked about the inclusion of preservative free documentation in the compounding of commercially available products. Ms. Sutcliffe stated that the definition comes from Federal Law. Ms. Sutcliffe stated that she could add “the same strength or slightly different without preservatives” to the definition.

Ms. Reed- Kane asked about compounding a medication because the patient could not afford the commercially available product. Ms. Carboni stated that a product should not be compounded for financial reasons.

Dr. Musil requested that the following language be added to the section on compounding commercially available products: “or produces a clinically therapeutic response”.

The task force members asked that the requirement to obtain the documentation for subsequent new prescriptions or refills be removed.

The task force members requested that Section (S) (3) (a) be eliminated. The pharmacy would determine the documentation to be used to determine if a product is unavailable and this would be designated in their policies and procedures.

The task force recommended adding Storage Information to the label for compounded products for office use in Section O.

In Section N, Dr. Musil recommended added to the language “ giving a written list of the product’s active ingredients to the patient at the time of dispensing and upon request of a practitioner”.

R4-23-670

Mr. Musil asked about the separate rooms. Ms. Sutcliffe stated that if an isolator is used a separate room is not need. Ms. Sutcliffe stated that the isolator must meet the class 7 environment

In Section A (2) (c), Ms. Sutcliffe stated that she is expanding the definitions to include coved.

The task force members asked Ms. Sutcliffe to include fungal components in Section G (7) and to include fungal testing in Section 8.

The task force discussed accrediting and certification of pharmacies and staff. The task force decided that this would take a statutory change and at this point would allow the Board to determine if the Board wanted to proceed with either process. The task force could not determine what body would be able to accredit all types of pharmacies.

The task force felt that the current 5% rule for office supply was insufficient. The task force would like to change the rule if possible. The change may also be a statutory change under wholesaling.

Call to the Public

Chairman Musil announced that interested parties have the opportunity at this time to address issues of concern to the task force; however the task force may not discuss or resolve any issues because the issues were not posted on the meeting agenda.

Mike Cavato , a Sales Representative, for Civic Center pharmacy indicated that he had concerns about the Senate Bill.

Mr. Musil stated that he would contact the Task Force Members concerning a future meeting.

The meeting adjourned at 4:10 P.M.